K110661

NOV 17 2011

OrthoAccel Technologies, Inc

AcceleDent™ System
TRADITIONAL 510(k) NOTIFICATION

510(k) Summary

AcceleDent™ System

November 15, 2011

This summary of 510(k) substantial equivalence determination is being submitted in accordance with the requirements of 21 CFR part 807.92.

Submitter: OrthoAccel® Technologies, Inc.
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Houston, TX 77054
Phone: 832-631-1657
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Contact: Michael E Kaufman

Device trade name:	AcceleDent™ System
Common name:	Orthodontic appliance and accessories
Classification name:	Orthodontic Vibratory Accessory
Classification:	Class II
Panel:	Dental
Product code:	OYH
Regulation number:	872.5470
Predicate device:	The Orthotrainer, K924975

Device Description:

The AcceleDent™ System is an orthodontic accessory for the treatment of tooth malocclusion. AcceleDent™ should be used by patients for twenty minutes per day in conjunction with standard orthodontic treatment with fixed appliances such as braces. The Activator and Mouthpiece assembly is light (2.7 oz or 75 g), comfortable, hands-free, and can be used while multi-tasking or while engaged in a variety of other daily activities. The most commonly reported multi-tasking use by patients was watching television, reading, using the computer, listening to music and doing homework.

Intended Use:

AcceleDent™ is an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement.

Characteristics Comparison:

A comparison of the AcceleDent™ System's indications for use with the predicate device indicates the AcceleDent™ System is substantially equivalent to currently marketed devices according to the following comparison:

- The general intended use of the device as an adjunct to orthodontics to facilitate tooth movement is the same as the OrthoTrainer.
- The indications for use to accelerate tooth movement during standard orthodontic treatment is a subset of the broader indications of the OrthoTrainer.
- The technological characteristics of the AcceleDent™ are very similar to the OrthoTrainer. Both are elastomeric devices that are held in the mouth for a sustained period each day.

Performance Testing:

Non-clinical and clinical performance testing completed with the AcceleDent™ System has demonstrated that the device performs safely and as intended.

Non-clinical performance testing completed:

- Output force testing
- Force testing
- Electromagnetic Compatibility and Electrical Safety
- Biocompatibility

A clinical study was performed to support this 510(k) Notification. The study was performed to determine whether teeth moved faster with standard orthodontics plus the AcceleDent™ device when compared to standard orthodontics plus a sham control.

Patients were followed at regular intervals to measure the rate of tooth movement until closure was achieved. Safety assessments also included evaluation of root resorption. The results of the study demonstrated that the AcceleDent™ increased the rate of tooth movement when used as an adjunct to conventional orthodontic treatment, and without any significant risks.

Conclusion:

Based on the results of non-clinical and clinical testing, the AcceleDent™ System performs safely, as intended, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael E. Kaufman
Vice President Marketing & Business Development
OrthoAccel Technologies, Incorporated
8275 El Rio, Suite 100
Houston, Texas 77054

NOV 17 2011

Re: K110661
Trade/Device Name: AcceleDent™ System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: OYH
Dated: November 9, 2011
Received: November 10, 2011

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110661

Device Name: AcceleDent™ System

Indication For Use:

AcceleDent is an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Device Evaluation (ODE)

Division Sign-Off

510(k)_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K110661